UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 15-13295-GAO

WILLIAM M. CODY, THOMAS S. NELSON, and JAMES SCHAEFER,
individually and on behalf of all others similarly situated
Plaintiffs,

v.

CONFORMIS, INC., PHILIPP LANG, and PAUL WEINER,
Defendants.

OPINION AND ORDER
August 3, 2016

O'TOOLE, D.J.

The plaintiffs, William M. Cody, Thomas S. Nelson, and James Schaefer,[1] bring claims under the Securities Act of 1933 and the Securities Exchange Act of 1934 (the "Securities Act" and the "Exchange Act," respectively) against the defendants, ConforMIS, Inc., Philipp Lang, and Paul Weiner. ConforMIS is a medical device company headquartered in Massachusetts. Lang is the company's President and Chief Executive Officer. Weiner is its Chief Financial Officer.

The defendants have moved to dismiss all claims against them. The primary Securities Act claim, brought under Section 11, see 15 U.S.C. § 77k, alleges material misstatements in or omissions from ConforMIS's prospectus, issued in connection with its initial public offering ("IPO"). The primary Exchange Act claim alleges a violation of Rule 10b-5, see 17 C.F.R. § 240.10b-5,[2] and alleges material misstatements or omissions in the company's prospectus and in a post-IPO earnings conference call that Lang and Weiner held with analysts and investors. The

[1] The current named plaintiffs were designated lead plaintiffs by the Court in the place of the original named plaintiff, Henry J. Klein (dkt. no. 15). See 15 U.S.C. § 78u-4(a)(3)(B).
[2] Rule 10b-5 implements Section 10(b) of the Exchange Act, see 15 U.S.C. § 78j(b).

plaintiffs also bring two derivative claims for officer or director liability against Lang and Weiner under Section 15 of the Securities Act and Section 20(a) of the Exchange Act. It appears undisputed that if the primary claims fail, so too do the individual liability claims.

For the reasons explained in more detail below, the plaintiffs have not adequately pled claims under either Section 11 or Rule 10b-5. Specifically, the Amended Complaint does not allege facts that would support a plausible conclusion that any of the challenged statements were false or misleading when made. Nor, as to the Exchange Act claims, do the factual allegations of the Amended Complaint support a strong inference of scienter, an essential element of a claim under Rule 10b-5.

I. Factual Background

The Amended Complaint alleges the following: ConforMIS manufactures and sells custom designed joint replacement devices, particularly knee replacement devices. The fundamental proposition of the company's business plan is that implants designed specifically for a particular patient are superior in performance to mass-produced "off-the-shelf" implants precisely because each ConforMIS device is designed to match the unique anatomical geometry of a specific person, leading to better clinical outcomes. In addition to the implant device itself, the company delivers to surgeons a set of instruments it dubs "iJigs" to be used in the implant surgery.

In the first half of 2015, ConforMIS operated manufacturing facilities in Bedford and Burlington, Massachusetts. At the time of its IPO, July 1, 2015, the company was in the process of shutting down its Burlington facility and transferring those operations to a new facility in Wilmington, Massachusetts. Primary manufacturing operations were transferred after the IPO.

As a medical device company, ConforMIS must comply with the Food and Drug Administration's QSR (Quality System Regulation) protocol. See generally 21 C.F.R., Part 820. The QSR does not itself establish a specific set of quality control rules, but rather requires a manufacturer of medical devices to establish and enforce policies and procedures sufficient to achieve effective quality control. In its prospectus, the company stated that it believed its existing Burlington and Bedford facilities were in compliance with the QSR. (The Wilmington facility was still in the process of being validated.)

An important part of ConforMIS's manufacturing process is the cleaning and sterilization of the iJigs, the surgical instruments that accompany the knee replacement devices. According to the Amended Complaint, the iJigs were first cleaned in-house and then sent out to a vendor to be sterilized. The Amended Complaint describes the process in some detail:

> 32. On information and belief, iJigs were cleaned ultrasonically in ConforMIS's facilities before being sterilized.
>
> 33. Ultrasonic cleaning usually has four steps: (1) submerging the item in cleaning solution; (2) introducing ultrasonic sound waves over a specific time period, which scrub the item clean as tiny bubbles rapidly form and then implode around the item; (3) rinsing off the solution; and (4) drying the item.
>
> 34. ConforMIS has used different sterilization methods at different times, including hydrogen-oxide sterilization and ethylene-oxide sterilization.
>
> 35. Ethylene-oxide sterilization is more efficient than hydrogen-peroxide sterilization, but ethylene-oxide sterilization has a much higher risk of leaving dangerous residues, including ethylene oxide itself, ethylene chlorohydrin, and ethylene glycol.
>
> 36. On information and belief, ConforMIS primarily used hydrogen-peroxide sterilization before its IPO.
>
> 37. At some point in 2014, ConforMIS decided to outsource its sterilization process to an outside vendor called STERIS.

> 38. After its IPO, ConforMIS began to rely more heavily on ethylene-oxide sterilization.

(Am. Compl. ¶¶ 32–38 (dkt. no. 23).) According to the Amended Complaint, the use of ethylene oxide in the sterilization process presents a risk that if the item is not thoroughly dried after its cleaning, the remaining moisture may lead to the formation of ethylene glycol, a moderately toxic type of antifreeze. (See id. ¶¶ 45–47.)

From the "Risk Factors" section of the prospectus, the plaintiffs cite the following statements by the company:

> We may encounter problems or delays in the manufacturing of our products or fail to meet certain regulatory requirements that could result in a material adverse effect on our business and financial results.
> . . .
> We may encounter other difficulties in increasing and expanding our manufacturing capacity, including difficulties:
> - acquiring raw materials for 3D printing;
> - deploying new manufacturing processes, including DMLS 3D printing;
> - acquiring 3D printers, especially DMLS 3D printers;
> - managing production yields;
> - **maintaining quality control and assurance;**
> - maintaining component availability;
> - **maintaining adequate control policies and procedures;**
> - hiring and retaining qualified personnel; and
> - complying with state, federal and foreign regulations.

(Mem. of Law in Supp. of Defs.' Mot. to Dismiss, Ex. A, at 31–32 (dkt. no. 29-2) (bold face supplied by plaintiffs);[3] Am. Compl. ¶¶ 95–96.)

In the "Business" section of the prospectus, under "Manufacturing," the plaintiffs point to the following statements:

[3] The prospectus, earnings call, and product recall press release are all extensively quoted in and incorporated by reference into the Amended Complaint and may be considered in full on a motion to dismiss. See A.G. ex rel. Maddox v. Elsevier, Inc., 732 F.3d 77, 80 (1st Cir. 2013).

> We conduct our manufacturing activities in state-of-the-art design and manufacturing facilities in Bedford, Burlington and Wilmington, Massachusetts.
> . . .
> ***Quality assurance***
> We apply a variety of automated and manual quality controls to our iJigs, implant components and other instruments we supply to ensure that our products conform to their specifications. **Members of our quality department also inspect our devices at various steps during the manufacturing cycle** to facilitate compliance with specifications. **Our quality department periodically audits our suppliers** to ensure conformity with our specifications and with our policies and procedures for our devices.
> We and our suppliers are subject to extensive regulation by the FDA under its Quality System Regulations, or QSR. The QSR provide that manufacturers must establish and follow quality systems consistent with the QSR framework to ensure that their products consistently meet applicable requirements and specifications. **In accordance with the QSR framework, we have validated or verified the processes used in the manufacturing and testing of our devices.** Our Burlington and Bedford manufacturing facilities are FDA registered, and **we believe they are compliant with the FDA's QSR**. We are in the process of completing our validations of our Wilmington facility and expect to register the facility with the FDA in the second quarter of 2015. We have also received certification from the British Standards Institution, or BSI, a Notified Body to the International Standards Organization of our quality system. Certification by a Notified Body is a necessary element of obtaining CE Marking in the EU. We are subject to periodic, announced and unannounced inspections by BSI, the FDA, and other governmental agencies. We continue to monitor our quality system and management efforts in order to maintain our overall level of compliance.

(Mem. of Law in Supp. of Defs.' Mot. to Dismiss, Ex. A, at 83–84 (header format in original and bold face supplied by plaintiffs); Am. Compl. ¶¶ 92–93.)

The plaintiffs argue that these statements were materially false or misleading when made because the defendants "stated that the Company 'may' encounter 'problems' . . . . But in reality, the Company was *already* experiencing numerous deficiencies and problems in these areas, which ultimately forced the Company to recall hundreds of its products." (Am. Compl. ¶ 97 (emphasis in original).)

On August 11, Lang and Weiner had what appears to be their first quarterly earnings call as a public company. Relevant only to the Exchange Act claims, the plaintiffs argue that several statements made by Lang or Weiner on that call were materially misleading.

On the call, Lang stated:

> Operationally we've made solid progress in Q2 by moving to our new manufacturing facility in Wilmington, Massachusetts. We expect that our move to the Wilmington facility will support our growth through 2018, and should have a positive impact on our gross margins by reducing our manufacturing and overhead cost structure.

(Am. Compl. ¶ 99.)

Later, Weiner responded to a question about "milestones from a manufacturing standpoint":

> Yes, Chris, we're comfortable with the product gross margins as far as increasing in the second half of the year to be pretty consistent with what we've done last year. The increase in the second half of the year over the first half of the year will be driven primarily by volume increases. As we look out further, then we're looking at vertical integration to assist with the increasing gross margins. So for the second half of the year, it would be primarily driven by volume increases. Also keep in mind that in addition, we have a lower overhead cost structure with the move to the Wilmington facility, paired with the streamlined operations that Wilmington offers, which will also help in this regard.

(Am. Compl. ¶ 100.)

Lang also stated, "in response to a question about vertical integration with respect to manufacturing, that 'with regard to the Wilmington facility, we've now really created the infrastructure, the operating base from which we can scale up our vertical integration.'" (Am. Compl. ¶ 101 (earnings call in internal quotation marks).)

Before the markets opened on August 31, 2015, ConforMIS announced a voluntary recall of some of its products. The press release said:

> [ConforMIS] today announced that it has initiated a voluntary recall of specific serial numbers of patient-specific instrumentation . . . . ConforMIS has initiated this action in response to three recent complaints of moisture on the patient-specific instrumentation. In all three cases, the knee replacement procedures were completed without apparent incident and the Company does not believe that the customized knee implants used in these procedures were themselves affected. . . .

> Based on an initial assessment, ConforMIS believes that the recalled instrumentation held excess water before undergoing the commonly used ethylene oxide sterilization process and, as a result, may contain small amounts of ethylene glycol residue.

(Am. Compl. ¶ 104).

This recall affected about 950 instrumentation sets. About 650 of those had already been used. There is no allegation that there were any reported adverse consequences with those surgeries. All the recalled equipment was manufactured at the Wilmington facility between July 18, 2015 and August 28, 2015.[4] As a result of the recall, the company reduced its revenue forecast for 2015, and the stock price quickly dropped from $19.78 at closing on Friday, August 28 to $16.00 at closing on Monday, August 31, the day of the announcement. The share price closed at $14.18 on September 2, the day before this suit was filed.

In addition to pointing to statements in the prospectus and by the individual defendants, the Amended Complaint sets forth allegations from six former ConforMIS employees who are characterized as "confidential witnesses" (or "CWs"). None of the six worked at the Wilmington facility where the recalled products were manufactured, and only one, CW 3, worked for the company at all after the July 1 IPO. (CW 3 apparently left at some unspecified time during July.) Thus, there is no allegation that any of the CWs worked in the facility where the recalled products were manufactured during the time they were manufactured.

The CWs describe managers pressuring workers to meet certain quotas by speeding up the manufacturing process, including by reducing the time for ultrasonic cleaning. The Amended Complaint states that "[b]y failing to ensure that the iJigs were dry before sterilization,

[4] The prospectus statements predated this period, while the earnings call occurred about mid-way through it.

[ConforMIS] created [a] risk that ethylene glycol residue would form on the instrumentation." (Am. Compl. ¶ 63.) No further specifics are alleged.

After cleaning at the ConforMIS facility, the instruments were sent to a third party, STERIS, for sterilization. "According to Confidential Witness 6, a Manufacturing Supervisor between May 2013 and February 2015, ConforMIS did not inspect its products for moisture or other contaminants after receiving them from STERIS and before shipping them to patients." (Am. Compl. ¶ 70.)

A couple of the CWs point to ConforMIS's Senior Vice President of Operations in 2015, Matthew Scott, as the driver of increased pressure on employees to speed production, with the implication that he urged cutting corners to achieve that goal. Scott is not a defendant here. He did not sign the prospectus and did not participate on the August 11 earnings call.

II. Discussion

As for any Rule 12(b)(6) motion, the Court accepts as true all well-pled factual allegations and evaluates whether the supporting factual allegations make each claim "plausible on its face." See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id.

Claims under Section 11 of the Securities Act must show simply that "any part of [a] registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k. The statute "imposes strict liability on

issuers" and does not contain a scienter or reliance element. See Silverstrand Invs. v. AMAG Pharm., Inc., 707 F.3d 95, 102 (1st Cir. 2013).

For the Section 11 claim, only the statements in the prospectus, as part of the registration statement, are potentially actionable. The plaintiffs do not allege that the defendants neglected to disclose something specifically required by rule, so the only potential avenues of liability are (1) "untrue statement[s]" and (2) omissions of information "necessary to make the statements [in the prospectus] not misleading."

With respect to the Exchange Act, a claim under Rule 10b-5 and Section 10(b) has six elements: (1) a material misrepresentation or omission, (2) scienter, (3) a connection with the purchase or sale of a security, (4) reliance (often fraud on the market), (5) economic loss, and (6) loss causation. See Mass. Ret. Sys. v. CVS Caremark Corp., 716 F.3d 229, 237 (1st Cir. 2013) (citing Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 341–42 (2005)). Exchange Act claims like those asserted here are subject to heightened pleading standards under Federal Rule of Civil Procedure 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). "The PSLRA requires plaintiffs to state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, i.e., the defendant's intention 'to deceive, manipulate, or defraud.'" Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 313 (2007) (citation and emphasis omitted).

For scienter, the PSLRA requires a heightened showing beyond what Rule 9(b) requires. "A plaintiff alleging fraud in a § 10(b) action . . . must plead facts rendering an inference of scienter *at least as likely as* any plausible opposing inference." Tellabs, 551 U.S. at 328 (emphasis in original).

In addition, the First Circuit has described the required state of mind necessary to support a finding of scienter as either actual intent to defraud or reckless disregard of the statement's falsity. See Greebel v. FTP Software, Inc., 194 F.3d 185, 198–99 (1st Cir. 1999). The Circuit has approved this formulation of recklessness:

> [R]eckless conduct may be defined as a highly unreasonable omission, involving not merely simple, or even inexcusable, negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious the actor must have been aware of it.

Id. at 198 (quoting Sundstrand Corp. v. Sun Chem. Corp., 553 F.2d 1033, 1045 (7th Cir. 1977) (alteration in original)). "[R]ecklessness does not encompass ordinary negligence and is closer to a lesser form of intent." Id. at 199.

This opinion will first address whether the Securities Act claims—which only involve evaluation of the prospectus statements—pass muster under Rules 8 and 12(b)(6). The analysis will then turn to whether the Amended Complaint satisfies the heightened pleading standards with respect to the Exchange Act claims—which involve both the prospectus and the earnings call statements.

A. Securities Act Claims

For their Section 11 claim, the plaintiffs fail to allege facts sufficient to support a plausible inference that the prospectus contained a material false statement or omitted a fact necessary to prevent the statements affirmatively made from being materially misleading.

First, the "risk factors" statements identified above are true on their face. Nowhere does the Amended Complaint allege that the statement that ConforMIS "may encounter . . . difficulties . . . maintaining quality control and assurance" was a false statement in and of itself. (Am. Compl.

¶ 96.) Indeed, it is essentially a truism. Investors be warned: Stuff happens. In complex manufacturing, events that disrupt orderly, planned processes can and do occur unexpectedly.[5]

The plaintiffs argue, instead, that a forward-looking statement that an event *may* happen can be materially misleading if the event is *already* happening. For support they point principally to two cases, In re Number Nine Visual Technology Corp. Securities Litigation, 51 F. Supp. 2d 1 (D. Mass. 1999), and In re Transkaryotic Therapies, Inc. Securities Litigation (TKT), 319 F. Supp. 2d 152 (D. Mass. 2004).

Their proposition is valid as a general matter, but it does not fit the facts alleged in this case. Number Nine involved a disclosure that a shortage of memory chips "in the future" could affect profits, when the company was, at the time, already experiencing such a shortage. 51 F. Supp. 2d at 23. In TKT, the company stated that the FDA might request additional data with regard to one of its products, when the FDA had in fact already recommended that the company provide information from "additional clinical studies." 319 F. Supp. 2d at 161 & n.10. In both cases, there was no contingency; the events predicted as possible had already actually occurred when the statements were made.

By contrast, there is no allegation here of any ongoing adverse event that would require disclosing that a contingency—"may happen"—was an actuality—"is happening." Specifically as to the two risk statements the plaintiffs emphasized in bold print in their Amended Complaint—that as the company expanded it might experience difficulties "maintaining quality control and assurance" and "maintaining adequate control policies and procedures"—there is no allegation

[5] In this sense, all the "risk factors" statements are forward-looking, and thus invoke the "bespeaks caution" doctrine. See Shaw v. Digital Equip. Corp., 82 F.3d 1194, 1213 & n.23 (1st Cir. 1996), abrogated on other grounds by 15 U.S.C. § 78u–4(b)(2).

that, on June 30, there were any *ongoing* manufacturing problems.[6] In particular, there is no allegation that as of the date of the prospectus anyone had yet complained about moisture on the iJigs. Cf. Silverstrand, 707 F.3d at 106 (declining to dismiss a Section 11 claim on account of company's failure to disclose twenty-three known adverse events linked to its drug).

What the plaintiffs do contend is that lax manufacturing procedures—and thus the risk created by those procedures—already existed at the time of the IPO and that "fact" should have been disclosed. But the Amended Complaint's allegations that are said to support this "fact" are far too general to meet the plausibility requirement of Rule 8. See Twombly, 550 U.S. at 556–58 (allegations must cross the line from possibility to plausibility); see also, Dura Pharm., 544 U.S. at 347–48. Even if the allegations based on reports from the CWs are credited, they do not support the conclusion that instruments were at the time being manufactured with inadequate care.[7]

Differences between the pre- and post-IPO operations also undermine the plausibility that even a person with perfect knowledge of all of ConforMIS's current operations on June 30, 2015, could have anticipated the ethylene glycol recall in late August. According to the Amended Complaint, the problematic ethylene oxide sterilization process became the primary means of sterilization only *after* the IPO. (See Am. Compl. ¶¶ 36–38.) Since ConforMIS was primarily using

[6] That there had been prior ConforMIS recalls cuts against the plaintiffs here for several reasons. (See Am. Compl. ¶¶ 79–84.) First, the recalls were isolated incidents that had occurred in the past—some, years before—and were not alleged to be ongoing. Second, none were even remotely related to moisture problems or sterilization procedures. Third, the fact itself that there had been prior recalls was disclosed in the prospectus. (Mem. of Law in Supp. of Defs.' Mot. to Dismiss, Ex. A, at 51.)

[7] As an example of the inadequacy of the general allegations based on the CWs' complaints, one complaint was that managers urged that total cleaning time be reduced from twenty minutes to ten minutes. Perhaps that was an instruction to "cut corners," or perhaps it was a recognition that ten minutes was sufficient to do the job and taking twenty minutes was an unnecessary inefficiency. From what is alleged in the Amended Complaint, it is not possible to know. Nor do the plaintiffs allege that, in cutting the overall cleaning time, the *drying* time was reduced. (See Am. Compl. ¶¶ 62–63.)

a different sterilizing agent—hydrogen peroxide—prior to the IPO, it is apparently not the case that as of the date of the prospectus the company was employing the procedures that actually led to the later recall. However lax manufacturing processes may have been at Burlington and Bedford, they did not, for all that is alleged, lead to the moisture problem encountered after manufacturing began at the Wilmington facility and the sterilizing agent was changed. None of the CWs ever worked at Wilmington and they supplied no information about practices there. So it is on speculation alone that the plaintiffs assert that the procedures in Wilmington were similar to the Burlington and Bedford procedures that the CWs disparaged.

All manufacturing processes entail risk, and the prospectus said essentially that. Lack of clairvoyance is not actionable, and the companies in Number Nine and TKT were not accused of a lack of clairvoyance. They were accused of describing an adverse event that had actually materialized as being only a potential risk. That is not what is alleged here. Apparently sterilizing surgical instruments with ethylene oxide carries some potential risk of the inadvertent production of ethylene glycol. The Amended Complaint does not allege that that potential risk had already actualized before the prospectus was issued. For a risk statement to be actionable for omitting material information, the risk at issue must have already materialized so that it was not just possible in the future but actual in the present.

Statements from the "Business" section of the prospectus also fail to create liability under the Securities Act. The plaintiffs emphasize a few phrases from the quality assurance section:

> Members of our quality department also inspect our devices at various steps during the manufacturing cycle . . . .
>
> Our quality department periodically audits our suppliers . . . .
>
> In accordance with the QSR framework, we have validated or verified the processes used in the manufacturing and testing of our devices.

> [W]e believe [the Bedford and Burlington facilities] are compliant with the FDA's QSR.

(Am. Compl. ¶ 93.)

Nowhere do the plaintiffs allege that these statements were not true. Certainly, a "literally accurate" statement may still in context be misleading. See Lucia v. Prospect St. High Income Portfolio, Inc., 36 F.3d 170, 175 (1st Cir. 1994). However, the statements identified by the plaintiffs are not technically or literally accurate but in a larger context equivalent to "material misrepresentation[s] by half-truth and incompleteness." See Backman v. Polaroid Corp., 910 F.2d 10, 16 (1st Cir. 1990). From the plaintiffs' pleadings it appears that each statement was true in context as well as in isolation.

The first statement represents that ConforMIS employees "inspect [its] devices at various steps." The Amended Complaint does not challenge that contention. Indeed, there is no discussion about ConforMIS's inspection practices at different stages of the manufacturing process. Instead, the plaintiffs point to a CW who claims that "ConforMIS did not inspect its products for moisture or other contaminants after receiving them from STERIS." (Am. Compl. ¶ 70.) That does not contradict or prove false the statement that the company inspects the devices "at various [unidentified] steps."

The same can be said about the "audits our suppliers" statement. The plaintiffs do not allege that no auditing occurred. Again, saying in a general way that auditing occurs is not inconsistent with the fact that the iJigs were not inspected post-sterilization.

The two QSR statements likewise contain no misstatement. The plaintiffs do not allege that the Burlington and Bedford plants did not have validated and verified processes. See 21 C.F.R. §§ 820.3(z), (aa) (defining "validation" and "verification"). The Amended Complaint baldly asserts that if the "manufacturing and quality-control processes had complied with the QSR, [ConforMIS]

would have established and followed procedures to ensure that it was not shipping surgical instruments with antifreeze on them." (Am. Compl. ¶ 64.) But recall, the QSR is a framework for implementing quality controls, not a foolproof set of specific guidelines that "ensure" or guarantee safety. (Accord Am. Compl. ¶ 42 ("The QSR provide a framework, and manufacturers are affirmatively required to develop and follow procedures and fill in the details . . . ." (citations and internal quotation mark omitted)).) And importantly, there is no specific allegation as to how ConforMIS's procedures were inconsistent with the requirements of the QSR. Simply alleging that there was a failure to meet the QSR standards without saying how does not meet the pleading standard of Rule 8. See Twombly, 550 U.S. at 557.

The plaintiffs also argue that the "we believe [the Bedford and Burlington facilities] are compliant with the FDA's QSR" statement contains an embedded statement of fact. See Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund, 135 S. Ct. 1318, 1327 (2015). The statement appears to be an unvarnished opinion. Indeed, that is likely why "we believe" was used, and a reasonable investor would understand that. See id. at 1328. There is nothing in the pleadings suggesting that the FDA had told ConforMIS otherwise, or that this opinion was not honestly held.[8] "[A] sincere statement of pure opinion is not an 'untrue statement of material fact' . . . ." Id. at 1327. Nor is there any indication that the purportedly "embedded" statement that Bedford and Burlington "are compliant" is itself factually untrue. The plaintiffs have not shown what further omitted statement might be required to avoid misleading investors.

[8] For their Securities Act claims, the plaintiffs abjure any theory based on fraud or intentional or reckless misconduct. (See, e.g., Am. Compl. ¶ 131.) Accordingly, there is no claim that the defendants did not in fact believe what they said they believed. See Omnicare, 135 S. Ct. at 1326.

Finally, looking at the quality assurance section as a whole, the plaintiffs argue that ConforMIS "devoted considerable space in the Prospectus to assure investors that [it] had strong quality controls and inspection processes in place." (Pls.' Opp'n to Defs.' Mot. to Dismiss 17 (dkt. no. 33).) However, review of the prospectus itself reveals that the quality assurance section consists entirely of two generally-worded paragraphs within a document that runs over 180 pages. This dramatic difference between the specificity of disclosures the plaintiffs claim were necessary and the actual disclosures' generality is an example of a central error in the plaintiffs' Section 11 case. Accurate disclosure in general terms of the nature and risks of its business does not, simply because of the generality, require a company like ConforMIS to then catalog every particular future issue that could be imagined. That would obviously be impractical; it would also be ultimately counterproductive. Over-disclosure may be just as obscuring as under-disclosure. See TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 448–49 (1976) ("[M]anagement's fear of exposing itself to substantial liability may cause it simply to bury the shareholders in an avalanche of trivial information—a result that is hardly conducive to informed decisionmaking.").

In sum, the plaintiffs have not adequately alleged that the prospectus contained a false statement or omitted information required to make its affirmative statements not misleading. The Amended Complaint does not with sufficient factual specificity allege that, as of June 30, 2015, there were any specific ongoing problems that the company was bound to disclose. The general, and at times highly cautionary, language of the prospectus is not "so incomplete as to mislead." See Backman, 910 F.2d at 16 (citation omitted). The Section 11 claim fails to state a claim upon which relief can be granted, and concomitantly, so does the Section 15 claim.[9]

[9] The defendants argue that the Securities Act claims "sound in fraud" and are thus subject to the heightened pleading requirements of Rule 9(b). See Silverstrand, 707 F.3d at 102. Because, taking

B. Exchange Act Claims

The Exchange Act claims fair no better. The prospectus statements are not materially misleading under the more stringent PSLRA standard, just as they are not under the Twombly/Iqbal standard.

The statements made by Lang and Weiner on the August earnings call are also a basis for the plaintiffs' Rule 10b-5 claim. General, puffing-type statements, such as, "we've made solid progress" and "lower overhead cost structure" typically do not support liability. However, it could be argued that, because these statements came during what was later identified as the product recall period, the possibility must be considered that the executives already knew of the moisture problem, so that these general statements were by reason of that knowledge misleading when made. However, the Amended Complaint fails to allege facts sufficient to support an inference that Lang or Weiner (or through them, ConforMIS) had the requisite knowledge or state of mind to commit securities fraud.

To succeed in their Exchange Act claims, the plaintiffs must "state with particularity facts giving rise to a strong inference" of scienter. 15 U.S.C § 78u-4(b)(2)(A). That inference must be "at least as compelling as any opposing inference one could draw from the facts alleged." Tellabs, 551 U.S. at 324. The Amended Complaint contains nothing of the sort. None of the CWs interacted with Lang or Weiner. The allegations in the Amended Complaint of shortened cleaning times, cutting corners, and high-pressure working conditions are not particular enough to show that any specific problem was known (or should have been known) by any managers, let alone the top executives of the company.

---

the Amended Complaint at its word, it fails to state an adequate Section 11 claim under Rule 8, fraudulent or otherwise, it is unnecessary to reach this issue.

> Absent from this case are the typical hallmarks of scienter.
>
> In cases where [the First Circuit has] found the pleading standard satisfied, the complaint often contains clear allegations of admissions, internal records or witnessed discussions suggesting that at the time they made the statements claimed to be misleading, the defendant officers were aware that they were withholding vital information or at least were warned by others that this was so.

In re Boston Sci. Corp. Sec. Litig., 686 F.3d 21, 31 (1st Cir. 2012). Those kinds of specific allegations are missing here. The Amended Complaint alleges no facts bearing on the mindset of the top executives of the company in August 2015. The plaintiffs are left simply to speculate as to what Lang and Weiner might have known or thought. That guesswork does not measure up to the standard required by the PSLRA.

For example, the argument that ConforMIS was a small company and thus the CEO and the CFO must have known of the manufacturing problems is insufficient. Over 350 people worked for ConforMIS at the time. The plaintiffs have pled nothing to indicate that Lang and Weiner were so intimately involved in the day-to-day details of the manufacturing processes that it would be a compelling inference that there was a known problem that was not being disclosed.[10] Possibility is not enough even for Rule 8, let alone the PSLRA standard.

Corporate scienter is likewise absent here, the plaintiffs' protestations concerning Scott, the Senior VP of Operations, notwithstanding. He did not participate on the earnings call (or sign the prospectus), and there are no allegations suggesting he had anything to do with what Lang and Weiner said during the call. Cf. Isham v. Perini Corp., 665 F. Supp. 2d 28, 36 (D. Mass. 2009) (refusing to find inference of scienter for a Vice President of Operations who had not "participated

[10] The case the plaintiffs cite for the proposition that executives of a smaller organization may know more detail is distinguishable for precisely this reason. Cf. Reese v. Malone, 747 F.3d 557, 572 (9th Cir. 2014) ("[T]he inference that [the executive] did not have access to the corrosion data is directly contradicted by the fact that she specifically addressed it in her statement. . . . In [her] role [as Performance Unit Leader], not only would [she] be aware of corrosion problems, but she would be among the first to know.").

in making, or had any knowledge of, the statements . . . that are the basis of Plaintiffs' allegations of fraud.").

Without a strong inference of scienter, there is no actionable Rule 10b-5 claim. While there may be other reasons as well, the plaintiffs' inability to adequately plead that necessary element of the claim means that the Exchange Act claims must be dismissed.

III. Conclusion

The plaintiffs request leave to amend their already Amended Complaint to avoid potential dismissal, yet they provide no basis for concluding that there are allegations available to them that might cure the pleading defects of the existing Complaint. The request to be allowed to replead is therefore denied. See Silverstrand, 707 F.3d at 107 ("Plaintiffs' request for leave to amend had one basic problem: it failed to abide by our oft-quoted maxim that litigants should not seriously expect to obtain a remedy without doing the necessary leg work first.").

The defendants' Motion to Dismiss the Amended Class Action Complaint (dkt. no. 28) is GRANTED in its entirety. This action is DISMISSED.

It is SO ORDERED.

/s/ George A. O'Toole, Jr.
United States District Judge